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United States District Court
Southern District of New York

7:19-cv-10860-KMK

Sherise Richardson, Dorianne Gatto, individually and on behalf of all others similarly situated,

Plaintiffs,

- against -

Mars Wrigley Confectionery US, LLC,

Defendant

First Amended Class Action Complaint

Plaintiffs by attorneys allege upon information and belief, except for allegations pertaining to plaintiffs, which are based on personal knowledge:

1. Mars Wrigley Confectionery US, LLC ("defendant") manufactures, distributes, markets, labels and sells chocolate coated bars of ice cream purporting to contain flavor only from its natural characterizing flavor, vanilla, under the M&M's brand ("Product").

2. The Product is available to consumers from retail and online stores of third-parties and is sold in boxes containing 6 bars of 1.63 FL OZ.

3. The relevant front label representations include "M&M's," "Vanilla" and "vanilla

reduced fat ice cream."

4. The designation of a food as "Vanilla Ice Cream" has been understood by consumers for over 50 years to identify a product where (1) vanilla is the characterizing flavor, (2) vanilla is contained in a sufficient amount to flavor the product, (3) the flavor is derived only from vanilla extract or vanilla flavoring and no other flavors simulate, resemble, reinforce, extend or enhance flavoring from vanilla or permit less real vanilla to be used.

5. Defendant's Product contains non-vanilla flavor, a de minimis amount of vanilla and to the extent it tastes like vanilla, such flavor is contributed by vanillin from non-vanilla sources.

6. The Product is not truthfully or lawfully identified as "Vanilla Reduced Fat Ice Cream" which misleads consumers.

I. Vanilla is Perennial Favorite Ice Cream Flavor

7. Ice cream is a year-round treat enjoyed by 96% of Americans.[1]

8. Its popularity is attributed "to the perfect combination of elements – sugar, fat, frozen water, and air – that make up the mouthwatering concoction."[2]

9. Until the early 1990s, any product named "ice cream" had to meet requirements of "not less than 10 percent milkfat, nor less than 10 percent nonfat milk solids."[3]

10. Vanilla is the consistent number one flavor for ice cream for 28% of Americans, confirmed two groups who would know – the International Dairy Foods Association (IDFA) (ice cream producers) and National Ice Cream Retailers Association (ice cream parlors).

11. The reasons for vanilla's staying power are "not only because it is creamy and delicious, but also because of its ability to enhance so many other desserts and treats."[4]

12. By some estimates, approximately two-thirds of "all ice cream eaten is either vanilla or vanilla with something stirred into it, like chocolate chips."[5]

13. The applications of vanilla ice cream include its centerpiece between chocolate wafers ("sandwich"), enrobed in chocolate on a stick ("bar"), topping a warm slice of fresh-baked

[1] Arwa Mahdawi, The big scoop: America's favorite ice-cream flavor, revealed, The Guardian, July 11, 2018
[2] Vox Creative, The Reason You Love Ice Cream So Much Is Simple: Science, Eater.com, October 12, 2017.
[3] 21 C.F.R. § 135.110(a)(2).
[4] Press Release, IDFA, Vanilla Reigns Supreme; Chocolate Flavors Dominate in Top Five Ice Cream Favorites Among Americans, July 1, 2018
[5] Bill Daley (the other one), Which vanilla ice cream is the cream of the crop? We taste test 12 top brands, Chicago Tribune, July 18, 2018

pie ("à la Mode"), drizzled with hot fudge, sprinkled with crushed nuts and topped by a maraschino cherry ("sundae") or dunked in a cold frothy glass of root beer ("float").[6]

I. Vanilla is Constantly Subject to Efforts at Imitation Due to High Demand

14. The tropical orchid of the genus Vanilla (*V. planifolia*) is the source of the prized flavor commonly known as vanilla,

15. Vanilla's "desirable flavor attributes…make it one of the most common ingredients used in the global marketplace, whether as a primary flavor, as a component of another flavor, or for its desirable aroma qualities."[7]

16. Though the Pure Food and Drugs Act of 1906 ("Pure Food Act") was enacted to "protect consumer health and prevent commercial fraud," this was but one episode in the perpetual struggle against those who have sought profit through sale of imitation and lower quality commodities, dressed up as the genuine articles.[8]

17. It was evident that protecting consumers from fraudulent vanilla would be challenging, as E. M. Chace, Assistant Chief of the Foods Division of the U.S. Department of Agriculture's Bureau of Chemistry, noted "There is at least three times as much vanilla consumed [in the United States] as all other flavors together."[9]

18. This demand could not be met by natural sources of vanilla, leading manufacturers to devise clever, deceptive and dangerous methods to imitate vanilla's flavor and appearance.

19. Today, headlines tell a story of a resurgent global threat of "food fraud" – from olive

[6] The True Wonders of Vanilla Ice Cream, FrozenDessertSupplies.com.
[7] Daphna Havkin-Frenkel, F.C. Bellanger, Eds., Handbook of Vanilla Science and Technology, Wiley, 2018.
[8] Berenstein, 412; some of the earliest recorded examples of food fraud include unscrupulous Roman merchants who sweetened wine with lead.
[9] E. M. Chace, "The Manufacture of Flavoring Extracts," Yearbook of the United States Department of Agriculture 1908 (Washington, DC: Government Printing Office, 1909) pp.333–42, 333 quoted in Nadia Berenstein, "Making a global sensation: Vanilla flavor, synthetic chemistry, and the meanings of purity," History of Science 54.4 (2016): 399-424 at 399.

oil made from cottonseeds to the horsemeat scandal in the European Union.[10]

20. Though "food fraud" has no agreed-upon definition, its typologies encompass an ever-expanding, often overlapping range of techniques with one common goal: giving consumers less than what they bargained for.

A. Food Fraud as Applied to Vanilla

21. Vanilla is considered a "high-risk [for food fraud] product because of the multiple market impact factors such as natural disasters in the source regions, unstable production, wide variability of quality and value of vanilla flavorings," second only to saffron in price.[11]

22. The efforts at imitating vanilla offers a lens to the types of food fraud regularly employed across the spectrum of valuable commodities in today's interconnected world.[12]

23. The highlighted entries describe deceptive practices used by defendant in selling and marketing its Vanilla Almondmilk.

Type of Food Fraud	Application to Vanilla
➢ Addition of markers specifically tested for	• Manipulation of the carbon isotope ratios to produce synthetic vanillin with similar carbon isotope composition to natural vanilla
➢ Appearance of *more* and/or higher quality of the valued ingredient	• Ground vanilla beans and/or seeds to provide visual appeal as "specks" so consumer thinks the product contains real vanilla beans, when the ground beans have been exhausted of flavor

[10] Jenny Eagle, 'Today's complex, fragmented, global food supply chains have led to an increase in food fraud', FoodNavigator.com, Feb. 20, 2019; M. Dourado et al., Do we really know what's in our plate?. Annals of Medicine, 51(sup1), 179-179 (May 2019); Aline Wisniewski et al., "How to tackle food fraud in official food control authorities in Germany." Journal of Consumer Protection and Food Safety: 1-10. June 11, 2019.
[11] Société Générale de Surveillance SA, ("SGS "), Authenticity Testing of Vanilla Flavors – Alignment Between Source Material, Claims and Regulation, May 2019.
[12] Kathleen Wybourn, DNV GL, Understanding Food Fraud and Mitigation Strategies, PowerPoint Presentation, Mar. 16, 2016.

- Caramel to darken the color of an imitation vanilla so it more closely resembles the hue of real vanilla[13]
- Annatto and turmeric extracts in dairy products purporting to be flavored with vanilla, which causes the color to better resemble the hue of rich, yellow butter

➢ Substitution and replacement of a high-quality ingredient with alternate ingredient of lower quality

- Tonka beans, though similar in appearance to vanilla beans, are banned from entry to the United States due to fraudulent use
- Coumarin, a toxic phytochemical found in Tonka beans, added to imitation vanillas to increase vanilla flavor perception

➢ Addition of less expensive substitute ingredient to mimic flavor of more valuable component

- Synthetically produced ethyl vanillin, from recycled paper, tree bark or coal tar, to imitate taste of real vanilla

➢ Compounding, Diluting, Extending

- "to mix flavor materials together at a special ratio in which they [sic] compliment each other to give the desirable aroma and taste"[14]
- Combination with flavoring substances such as propenyl guaethol ("Vanitrope"), a "flavoring agent [, also] unconnected to vanilla beans or vanillin, but unmistakably producing the sensation of vanilla"[15]

[13] Renée Johnson, "Food fraud and economically motivated adulteration of food and food ingredients." Congressional Research Service R43358, January 10, 2014.
[14] Chee-Teck Tan, "Physical Chemistry in Flavor Products Preparation: An Overview" in Flavor Technology, ACS Symposium Series, Vol. 610 1995. 1-17.
[15] Berenstein, 423.

	• "Spiking" or "fortification" of vanilla through addition of natural and artificial flavors including vanillin, which simulates vanilla taste but obtained from tree bark
➢ Addition of fillers to give the impression there is more of the product than there actually is	• Injection of vanilla beans with mercury, a poisonous substance, to raise the weight of vanilla beans, alleged in *International Flavors and Fragrances (IFF), Inc. v. Day Pitney LLP and Robert G. Rose*, 2005, Docket Number L-4486-09, Superior Court of New Jersey, Middlesex County
➢ Ingredient List Deception[16]	• Subtle, yet deliberate misidentification and obfuscation of a product's components and qualities as they appear on the ingredient list o "ground vanilla beans" gives impression it describes unexhausted vanilla beans when actually it is devoid of flavor and used for aesthetics o "natural vanilla flavorings" – "-ing" as suffix referring to something *like* that which is described o "Vanilla With Other Natural Flavors" – implying – wrongly – such a product has a sufficient amount of vanilla to characterize the food o "Natural Flavors" – containing "natural vanillin" derived not from vanilla beans but from tree pulp. When paired with real vanilla, vanillin is required to be declared as an artificial flavor[17] o "Non-Characterizing" flavors which are not identical to vanilla, but that extend vanilla

24. The "plasticity of legal reasoning" with respect to food fraud epitomize what H.

[16] A recent example of this would be "evaporated cane juice" as a more healthful sounding term to consumers to identify sugar.

[17] The numerous "naturally produced vanillins" are just as potent as their synthetic predecessors, such that "one ounce of vanillin is equal to a full gallon of single-fold vanilla extract."

Mansfield Robinson and Cecil H. Cribb noted in 1895 in the context of Victorian England:

> the most striking feature of the latter-day sophisticator of foods is his knowledge of the law and his skill in evading it. If a legal limit on strength or quality be fixed for any substance (as in the case of spirits), he carefully brings his goods right down to it, and perhaps just so little below that no magistrate would convict him.
>
> *The law and chemistry of food and drugs*. London: F.J. Rebman at p. 320.[18]

II. Standards of Identity for Ice Cream, Vanilla and Vanilla Ice Cream

25. Standards of identity for foods were established to protect consumers from economic adulteration – the substitution of more valuable ingredients and replacement with less valuable and harmful ones. *See* 21 U.S.C. § 343(g).

26. The requirement is expressed in 21 U.S.C. §343(g):[19]

> A food shall be deemed to be misbranded –
>
> (g) Representation as to definition and standard of identity
>
> If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

27. Standards of identity are described as "recipe" standards because they require standardized foods to contain specific ingredients in specific amounts.

28. Standards of identity reflect a recognition by Congress of the inability of consumers to determine the relative merits of a variety of products superficially resembling each other based on informative labeling in places other than a product's front label, such as from an ingredient list.

29. Standards of identity also reflect the intention of Congress to preclude manufacturers and courts from determining for themselves whether a food purporting to be a standardized food

[18] Cited in Sébastien Rioux, "Capitalist food production and the rise of legal adulteration: Regulating food standards in 19th-century Britain," Journal of Agrarian Change 19.1 (2019) at p. 65 (64-81).
[19] 21 U.S.C. § 343(g)(2) read with 21 C.F.R. § 135.110(f)(2)(i) and 21 C.F.R. §§ 169.175 – 169.178.

was permitted to contain different ingredients or different amounts of ingredients and determine consumers could not have been misled due to a product which deviated from a standard.

30. Standards of identity are a bulwark against consumer deception for reasons not limited to the following:[20]

1. Preventing confusion by reducing uncertainty faced by consumers making purchasing decisions and must select amongst numerous similarly labeled products;
2. Eliminating possibility of economic adulteration of standardized foods through substitution of lower quality ingredients;
3. Increasing the informational value of a product name, i.e., "vanilla," through restricting the range of information that can be conveyed by that product name;
4. Once a food has been standardized, the product name associated with that food, i.e., "vanilla," acquires a precise and specific meaning that it did not have prior to the creation of the standard.

31. New York State has adopted and incorporated in its entirety, all provisions of the Federal Food, Drug and Cosmetic Act ("FFDCA") through its Agriculture and Markets Law ("AGM") and the accompanying regulations. *See* Title 1, Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR").

32. New York Agriculture and Markets Law ("AGM") § 71-a ("Declaration of policy") is unambiguous that ice cream labeling cannot deviate from the federal regulations:

[20] Christopher Chen, "Food and drug administration food standards of identity: Consumer protection through the regulation of product information." Food & Drug LJ 47 (1992): 185.

> It is further declared to be in the interest of the dairy industry and of the consuming public that there be *uniformity of standards for frozen desserts as between the various states and the federal government* to the end that there may be free movement of frozen desserts between the states and to the end that the inefficiency, needless expense, and confusion caused by differences in products sold under the same name, and *differences in labeling of identical products may be eliminated*. (emphasis added).

33. The ice cream regulations state:

> The standards of identity for ice cream and frozen custard, goat's milk ice cream, ice milk, goat's milk ice milk, mellorine, sherbet, and water ices as set forth in sections 135.110, 135.115, 135.120, 135.125, 135.130, 135.140 and 135.160, respectively, of title 21 of the Code of Federal Regulations (revised as of April 1, 2010) are *adopted and incorporated by reference* herein.
>
> 1 NYCRR § 17.19, Additional standards of identity for frozen desserts at Chapter I ("Milk Control*), Subchapter A ("Dairy Products"), Part 17 ("Requirements for the Labeling of, and Definitions and Standards of Identity for, Milk, Milk Products and Frozen Desserts") (emphasis added).

34. The vanilla standards are adopted and incorporated verbatim into New York law:

> the commissioner hereby adopts the following as the standards of identity and/or standards of quality, and tolerances for food and food products as published in title 21 of the Code of Federal Regulations…21 CFR part 169, containing the Federal definitions and standards for *Food Dressings and Flavorings* at pages 600-606.
>
> 1 NYCRR § 250.1(a)(17) at Chapter VI ("Food Control"), Subchapter C, Food and Food Products, Part 250, ("Definitions and Standards").

35. The result is that the New York State labeling requirements for vanilla products is identical to those established by the FDA.

A. Vanilla's Usage and Labeling in Ice Cream

36. In debates accompanying the establishment of ice cream standards, the key issue before Congress was whether the flavor source was from the characterizing flavor – i.e., raspberry for raspberry ice cream, vanilla for vanilla ice cream.

37. Why, industry asked, could they not label their products as "vanilla ice cream" if it contained vanillin from sources other than vanilla beans?

38. In response, Congressmen E.A. Kenny of New Jersey and Virgil Chapman of Kentucky inquired of ice cream's representative, Mr. Schmidt:

> Mr. Kenney: Do you not think, though, Mr. Schmidt, that if you label it vanilla ice cream, it ought to be vanilla; and if it is made with vanillin extracted from oil of cloves, you ought to label it manufactured with such vanillin?
>
> Mr. Schmidt: Well, we, of course, do not think so. That is why we are here making our protest. We think, after all, the consuming public is accustomed to accepting as vanilla artificial vanillas.
>
> Mr. Kenney: *We agree that Barnum educated us along that line a long time ago.* (emphasis added)
>
> ……
>
> Mr. Chapman: I do think that if it is chocolate it ought to be labeled "chocolate"; and if it is flavored with vanillin made from oil of cloves, it ought to be labeled to show that it is flavored with vanillin made from oil of cloves; and if it is flavored with vanilla, it ought to be labeled "vanilla"; and if it is flavored with lemon, it ought to be labeled lemon; and if it is cherry, it ought to be labeled "cherry."

39. Later in the hearing, Mr. Chapman and another industry representative engaged over the proper declaration of flavor for ice cream:

> Mr. Chapman: Do you make raspberry?
>
> Mr. Hibben: Yes.
>
> Mr. Chapman: And you put that on the label?
>
> Mr. Hibben: We say "raspberry ice cream."
>
> Mr. Chapman: And if it is peach, you put that on the label?
>
> Mr. Hibben: It is peach ice cream; yes.
>
> Mr. Chapman: And If you call it vanilla, what do you put on?
>
> Mr. Hibben: We put "vanilla ice cream" on our labels. That is what we

want to continue to do. We want to put vanilla on those labels.

Mr. Chapman: But you say you put in it oil of cloves instead of vanilla.

Mr. Hibben: We do not use cloves. We use vanillin derived from the oil of cloves.

Mr. Chapman: If you put out strawberry ice-cream, you would not want to use raspberry to make it, would you?

Mr. Hibben: No; but we use vanillin, which is an ingredient of the vanilla bean and, its true to name.

Mr. Chapman: Is it an extract from the vanilla bean?

Mr. Hibben: It is both. It is taken both from the eugenol and the vanilla bean and is the same product. If you were a chemist you could not tell the difference, and if you were a doctor, you would say that one is just as harmless as the other.

Mr. Chapman: I do not object to buying artificial vanilla ice cream if it is pure, but if it is artificial. I would like to know what I am getting.

40. Since most of the vanilla used in the United States was for the flavoring of ice cream, the establishment of vanilla standards was intended to prevent companies from giving less vanilla than they expected. *See* 21 C.F.R. Part 169 ("Food dressings and flavorings"); 21 C.F.R. §169.3 ("Definitions"); 21 C.F.R. § 169.175 – 21 C.F.R. § 169.182 (vanilla products).

41. Prior to adoption of vanilla standards, "the widespread and exceedingly serious adulteration of vanilla extracts that are now labeled 'pure'…deprive[d] the consumer of value the product is represented to have, and for which the consumer pays.[21]

42. The vanilla standards were intended to "insure, for the protection of both the consumers and our industry, that all vanilla products are correctly labeled and meet at least

[21] Letter from McCormick & Company Inc. to HEW Secretary, January 15, 1960; Memorandum of Telephone Conversation between Mr. Alfred Daibock, Commercial Policy Division, Department of State and Tom Bellis, Food Standards Branch, FDA (the FDA stated, "The prime purpose sought to be served by the standards adopted was to promote honest, fair dealing with housewives and other consumers of the flavorings covered by the standards").

minimum standards."[22]

43. The objective basis for the standards is the requirement that a "*unit of vanilla constituent* means the total sapid and odorous principles extractable from one unit weight of vanilla beans," or 13.35 ounces.[23]

III. Shortage of Vanilla Leads to Cut Corners and Consumer Deception

44. For decades, The Flavor and Extract Manufacturers Association ("FEMA") successfully protected consumers from misleading and fraudulent vanilla labeling through a system of "self-policing" where companies were held accountable to industry standards which followed federal regulations.

45. However, FEMA was strong-armed into abandoning these efforts and disbanding its Vanilla Committee due to alleged financial pressure from its largest members.

46. Into this gap, flavor and food companies quickly reverted to practices which had been eradicated with the promulgation of the vanilla standards in the early 1960s.

47. The flavor industry benefits from high vanilla prices and the use of less real vanilla.

48. The recent global shortage of vanilla beans has provided the flavor industry another opportunity to "innovate[ing] natural vanilla solutions…to protect our existing customers."[24]

49. When less vanilla is available, customers of flavor companies – food manufacturers – must purchase higher margin, proprietary, "vanilla-like" flavorings made with advanced technology and synthetic biology.

50. According to Suzanne Johnson, vice president of research at a North Carolina

[22] Letter from McCormick & Company Inc. to HEW Secretary, January 15, 1960; Press Release U.S. Department of Health, Education, and Welfare, September 13, 1963.
[23] 21 C.F.R. §169.3(c) referencing 21 C.F.R. §169.3(b).
[24] Amanda Del Buouno, Ingredient Spotlight, Beverage Industry, Oct. 3, 2016.

laboratory, "Many companies are trying to switch to natural vanilla with other natural flavors [WONF] in order to keep a high-quality taste at a lower price," known as "Vanilla WONF."

51. The head of "taste solutions" at Irish conglomerate Kerry plc, urged flavor manufacturers to "[G]et creative" and "build a compounded vanilla flavor with other natural flavors."

52. A compounded vanilla flavor "that matches the taste of pure vanilla natural extracts" can supposedly "provide the same vanilla taste expectation while requiring a smaller quantity of vanilla beans. The result is a greater consistency in pricing, availability and quality."[25]

53. These compounded flavors exist in a "black box" with "as many as 100 or more flavor ingredients," including "naturally produced vanillin," potentiators and enhancers, like maltol and piperonal, blended together to enhance the vanilla, allowing the use of less vanilla to achieve the intended taste.[26]

IV. "Vanilla Ice Cream" Without Qualification Tells Consumers All of Product's Flavor and Vanilla Taste is from Vanilla Beans

54. According to John B. Hallagan and Joanna Drake, the former and current legal advisors for The Flavor and Extract Manufacturers Association of the United States ("FEMA"):

> When consumers purchase ice cream labeled as "vanilla ice cream" they expect it to be flavored with vanilla flavoring derived from vanilla beans *unless labeled otherwise*. As we shall see, this expectation is codified in two U.S. federal standards of identity, one for vanilla flavorings and one for ice cream.[27] (emphasis added).

55. Daphna Havkin-Frenkel, editor of the *Handbook of Vanilla Science and Technology*,

[25] Donna Berry, Understanding the limitations of natural flavors, BakingBusiness.com, Jan. 16, 2018.
[26] Hallagan and Drake, FEMA GRAS and U.S. Regulatory Authority: U.S. Flavor and Food Labeling Implications, Perfumer & Flavorist, Oct. 25, 2018; Charles Zapsalis et al., *Food chemistry and nutritional biochemistry*. Wiley, 1985, p. 611 (describing the flavor industry's goal to develop vanilla compound flavors "That *Seem*[s] to be Authentic or at Least Derived from a Natural Source") (emphasis added).
[27] John B. Hallagan and Joanna Drake, The Flavor and Extract Manufacturers Association of the United States, "Labeling Vanilla Flavorings and Vanilla-Flavored Foods in the U.S.," Perfumer & Flavorist, Apr. 25, 2018.

and a leading scholar and researcher on vanilla, summarized these categories:[28]

> [A]s defined by the FDA Standard of Identity…Vanilla ice cream Category I contains only vanilla extract. Vanilla ice cream Category II contains vanilla made up of 1 oz of synthetic vanillin per 1 gallon of 1-fold vanilla extract. Vanilla ice cream Category III contains synthetic ingredients.

56. Carol McBride, U.S. vanilla category manager for global flavor giant Symrise, echoed these requirements and their effect on consumers: "If the flavor comes partially or fully from another source, the company must stamp 'vanilla flavored' or 'artificial vanilla' on the front of the package, a likely turnoff to consumers."[29]

57. The "Category 1" requirements are codified at 21 C.F.R. § 135.110(f)(2)(i), which states:

> If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the words "ice cream".

58. That the ice cream regulations are meant to be read "together with the vanilla standard of identity means that the characterizing flavor for this [Category 1] ice cream must be provided only by vanilla extract complying with the standard at 21 CFR Section 169.175, or another standardized vanilla flavoring derived solely from vanilla beans."[30]

59. Because the Product is "identified as 'Vanilla Ice Cream,' [it] is subject to the category I ice cream requirements and, therefore, must contain only the characterizing flavor derived from vanilla beans." Exhibit "A," Letter from J.L. Summers, Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods to David B. Daugherty, Zink & Triest

[28] Daphna Havkin-Frenkel and Faith C. Belanger, eds., *Handbook of Vanilla Science and Technology*, Wiley, 2018 (221).
[29] Melody M. Bomgardner, "The problem with vanilla," Chemical & Engineering News, Sept. 12, 2016.
[30] Hallagan, *supra* note 3, at p. 11.

Company, Inc., April 10, 1979 ("Summers Letter, April 10, 1979").

60. As Dr. Mark Black points out,

> Because vanilla is a defined food, the CFR links the ice cream rules (21 CFR 1:135) to the vanilla rules (21 CFR 1:169) through the three-tiered nomenclature. However, the CFR does not call this out in the ice cream rules. Indeed, vanilla extract is not mentioned in any other part of the ice cream rules.
>
> Exhibit "B," p.3, Mark Black, "The Use of Vanilla in Ice Cream: Rules, Regulations and Interpretations – All Are Needed For A Thorough Understanding."

61. The International Dairy Foods Association ("IDFA") summarized the unique distinction between natural and artificial flavors in the context of ice cream as follows:

> Flavors which are derived from natural sources other than the characterizing flavor and simulate, resemble or reinforce the characterizing flavor, are considered artificial flavors. Products flavored in such a manner must be labeled according to either flavor labeling requirements of Category II or III products.[31]

62. Though the text of 21 C.F.R. § 135.110(f)(2)(i) does not distinguish between flavor from the natural characterizing flavor and natural flavors from sources other than the characterizing flavor, the regulations for vanilla and ice cream products "are supplemented by a formal [Food and Drug Administration ('FDA')] Advisory Opinion, and a collection of FDA-issued regulatory correspondence."[32]

63. Dr. Black summarized the labeling questions addressed in the early 1980s:

> The industry sought clarification of these rules from the U.S. Food and Drug Administration (FDA). From 1979 to 1983, the FDA provided interpretations and ultimately an advisory opinion that clarified the rules around each category. However these have not been widely circulated, thus many ice cream manufacturers continue to be unsure about the legal status of their principal display panels.) (emphasis added).
>
> *See* Exhibit "B," p.3, "The Use of Vanilla in Ice Cream: Rules, Regulations and Interpretations – All Are Needed For A Thorough Understanding"

[31] IDFA, Ice Cream & Frozen Desserts Labeling Manual, 2019 Ed.
[32] Hallagan, *supra* note 3, at p. 1.

64. The 1983 Advisory Opinion referenced by Hallagan and Drake and Black was issued by Joseph Hile, Associate Commissioner for Regulatory Affairs, and reaffirmed a 1981 advisory opinion, which further confirmed the interpretation in a 1979 letter to industry members:

> The Newberry letter is correct under 21 CFR 135.110(e).[33] Because that section makes no provision for any natural flavors other than natural characterizing flavors, FDA must treat all natural flavors that simulate the characterizing flavor as artificial flavors when deciding what name should appear on the principal display panel.
>
> Exhibit "C," Advisory Opinion Letter from Hile to industry members, February 9, 1983 ("February 9, 1983 Advisory Opinion") citing Exhibit "D," Letter from R.E. Newberry, Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods to Thompson, October 30, 1979 ("Newberry Letter"); Exhibit "E," Advisory Opinion Letter from Hile to Adams, FEMA President, February 12, 1981 ("February 12, 1981 Advisory Opinion").

65. Both Hile letters were "specifically identified as [an] advisory opinions," and "represent[s] the formal position of FDA on a matter and except as provided in paragraph (f) of this section, obligates the agency to follow it until it is amended or revoked." *See* 21 C.F.R. § 10.85(d)(4), 21 C.F.R. § 10.85(e).

66. While advisory opinions are not a "legal requirement," they provide clarification to a complex labeling regime for vanilla ice cream. *See* 21 C.F.R. § 10.85(j).

67. The Product is represented as a Category 1 product because "the name on the principal display panel or panels of the label" is "accompanied by the common or usual name of the characterizing flavor, e.g., 'vanilla.'"

[33] 21 C.F.R. § 135.110(f) was previously 21 C.F.R. § 135.110(e).

68. The Product's ingredient list reveals the reduced fat vanilla ice cream in the Product is flavored by the ingredient designated as "Natural Flavors."

Ingredient List

INGREDIENTS: **REDUCED FAT ICE CREAM:** SKIM MILK, CREAM, SUGAR, CORN SYRUP, WHEY, MONO AND DIGLYCERIDES, CAROB BEAN GUM, GUAR GUM, CARRAGEENAN, ANNATTO EXTRACT (COLOR), NATURAL FLAVOR. **COATING:** SUGAR, COCONUT OIL, MILK, LACTOSE, PALM OIL, CHOCOLATE, COCOA POWDER, SOY LECITHIN, ARTIFICIAL FLAVOR. **COATED M&M MINIS MILK CHOCOLATE CANDIES:** [MILK CHOCOLATE (SUGAR, CHOCOLATE, SKIM MILK, COCOA BUTTER, LACTOSE, MILKFAT, SOY LECITHIN, SALT, ARTIFICIAL AND NATURAL FLAVORS), SUGAR, COLORING (INCLUDES BLUE 1 LAKE, RED 40, YELLOW 6, YELLOW 5, BLUE 1, RED 40 LAKE, YELLOW 6 LAKE, YELLOW 5 LAKE, BLUE 2 LAKE, BLUE 2), CORN SYRUP, DEXTRIN, CORNSTARCH, CARNUBA WAX], COCOA BUTTER.

69. Since a product labeled "vanilla ice cream" (Category 1) "purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title," it is required to list the "the common names of optional ingredients (other than spices, flavoring, and coloring)" 21 U.S.C. §343(g).

70. The ice cream standard of identity also requires that the common name of the flavor

ingredients be "declared on the label as required by the applicable sections of parts 101 and 130."

71. The "common names of optional ingredients" in ice cream are those ingredients the manufacturer chooses to use to provide flavor, such as strawberries, peaches or vanilla extract. *See* 21 C.F.R. § 135.110(g).

72. Part 101 states:

> Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by 101.100, shall be listed by common or usual name.

21 C.F.R. § 101.4(a)(1)

73. Vanilla is the only flavor that has a standard of identity and is required to be identified by its common or usual name, which lets consumers know what they are getting. *See* 21 C.F.R. § 169.175(b)(1) ("The specified name of the food is 'Vanilla extract' or 'Extract of vanilla'."); *see also* 21 C.F.R. § 169.177(b) ("The specified name of the food is 'Vanilla flavoring.'").

74. Flavorings other than vanilla "shall be declared according to the provisions of 101.22." 21 C.F.R. § 101.4(b)(1); 21 C.F.R. § 101.22(h)(1) ("The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way…Spice, natural flavor, and artificial flavor may be declared as "spice", "natural flavor", or "artificial flavor", or any combination thereof, as the case may be.").

75. The Product does not list "vanilla extract" or "vanilla flavoring" because the "natural flavor" is not an exclusively vanilla ingredient.

76. The Product "is subject to the category I ice cream requirements and, therefore, must contain only the characterizing flavor derived from vanilla beans." Exhibit "A," Summers Letter, April 10, 1979.

V. GC-MS Analysis Reveals *de minimis* Amount of Vanilla but High Levels of Artificial Vanilla Flavoring

77. Using gas chromatography-mass spectrometry ("GC-MS"), the volatile flavoring compounds from the Product can be identified and quantified.

78. GC-MS is "the analysis method of choice" which has "proven its worth for the analysis of vanilla constituents."[34]

79. However, the "main vanilla flavor backbone of commercial vanilla species is constituted by the so called marker compounds: vanillin, *p*-hydroxybenzaldehyde, vanillic acid, and *p*-hydroxybenzoic acid" with their ratios – identified in the below table – "used as an indicator of quality of commercial vanilla to detect adulteration of beans and extracts."[35]

Compounds	Percent Present in Vanilla Beans
vanillin	1.3-1.7 %
p-hydroxybenzaldehyde	0.1%
vanillic acid	0.05%
p-hydroxybenzoic acid	0.03%

80. The Product was converted to a vapor and purged with inert gas ("Purge & Trap Method"), causing the volatile aromatic compounds to be extracted.

81. These compounds were run through capillary columns and eluted at different times before reaching the mass spectrometer.

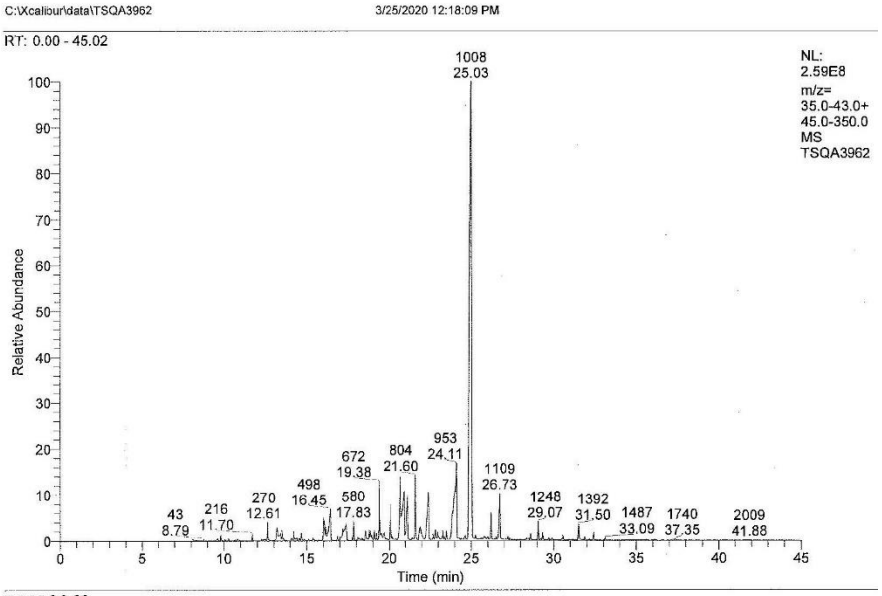
82. The mass spectrum plots the compounds' elution time on the X-axis and the amount

[34] ThermoFisher Scientific, Gas Chromatography Mass Spectrometry (GC/MS) Information; Arun K. Sinha et al. "A comprehensive review on vanilla flavor: extraction, isolation and quantification of vanillin and others constituents," International Journal of Food Sciences and Nutrition 59.4 (2008): 308; 299-326.

[35] Maria del Pilar Galeas, "Gas chromatography-mass spectrometry and gas chromatography-olfactometry analysis of aroma compounds of vanilla pompona schiede," Diss. Rutgers University-Graduate School-New Brunswick, 2015 citing A.S. Ranadive, Vanilla-cultivation, curing, chemistry, technology and commercial product. In: Spices Herbs and Edible Fungi. Charalambous, G. (Ed), Developments in Food Science, Vol. 34, Elsevier Science Publishers BV, Amsterdam, The Netherlands, pp 517-577 (1994).

or intensity of the compounds on the Y-axis. Exhibit "F," GC-MS Report, April 17, 2020.

Chromatogram



TSQA3962
Type: Unknown ID: 1 Row: 1

Sample Name:	Mars M&M Vanilla Ice Cream Bar (Production Code: 831 BBBUR09), DCM Extract, 150C/30min, matrix spiked with w/w 1.Cppm Int. Std. by P&T-TD-GC-MS
Study:	
Client:	Sheehan & Associates, P.C., LLN7638
Laboratory:	Mass Spectrometry - Dr. Tom Hartman
Company:	
Phone:	
Instrument Method:	C:\Xcalibur\methods\voc45solventdelay8min.meth
Processing Method:	
Vial:	1
Injection Volume (µl):	10.00
Sample Weight:	0.00
Sample Volume (µl):	0.00
ISTD Amount:	0.00
Dil Factor:	1.00

83. The peak assignment table identifies the compounds in column three (peak assignment) by matching their mass-to-charge (m/z) ratio with mass spectral libraries of all known compounds.

84. Columns two (Area Integration) and four (concentration parts per million or "Conc. PPM w/w.") shows the relative amounts of the detected compounds.

Peak Assignment Table

Table 1

Sheehan & Associates, P.C., Project #7638
Mars M&M Vanilla Ice Cream Bar (Vanilla Ice Cream Harvested from Bar Interior)
Production Code: 831 BBBUR09
Methylene Chloride Extract of 10.0 g with 1 ppm Matrix-Spiked int. Std. by P&T-TD-GC-MS

Data File = TSQA3962

MS Scan #	Area Integration	Peak Assignment	Conc. PPM w/w
93	140002	acetic acid	0.083
119	37887	2-methylbutanal	0.023
216	137789	acetoin	0.082
229	12361	3-methyl-1-butanol	0.007
249	30258	1,2-propylene glycol	0.018
263	119520	isobutyric acid	0.071
307	760846	1,3-butanediol	0.453
319	465517	butyric acid	0.277
358	38005	methyl pyrazine	0.023
366	173686	furfural	0.103
377	137587	3-methylbutyric acid	0.082
385	76204	2-methylbutyric acid	0.045
393	173363	furfuryl alcohol	0.103
419	21610	pentanoic acid	0.013
435	87685	2-heptanone	0.052
452	19667	heptanal	0.012
468	19153	2-acetyl furan	0.011
473	916453	2,6-dimethyl pyrazine	0.545
480	228219	2,3-dimethyl pyrazine	0.136
498	1867109	dimethyl sulfone	1.110
532	109877	5-methyl furfural	0.065
542	503609	benzaldehyde	0.300
555	1422449	hexanoic acid	0.846
561	11044	2-pentylfuran + dimethyl trisulfide	0.007
575	51935	2-ethyl-6-methylpyrazine	0.031
580	396849	trimethyl pyrazine	0.236
595	85965	2-pyrrole carboxaldehyde	0.051
611	46419	cyclotene	0.028
616	4580	limonene	0.003
623	302598	benzyl alcohol	0.180
641	203726	furaneol	0.121
645	136338	heptanoic acid	0.081
655	271255	2-acetyl pyrrole	0.161
663	135720	ethyl dimethyl pyrazine isomer	0.081
672	1386479	tetramethyl pyrazine + trace of guiaicol	0.825
680	351641	gamma-heptlactone + nonanal	0.209
690	389109	dihydro-3,5-dimethyl-2(3H)-furanone	0.231
713	1264007	maltol	0.752
720	95436	1-methyl-1H-pyrrole carboxaldehyde	0.057
750	2263779	4H-pyran-4-one, 2,3-dihydro-3,5-dihydroxy-6-methyl (sugar thermal degradation product)	1.346
765	3607923	octanoic acid	2.146
777	1836230	benzoic acid	1.092
804	1681402	naphthalene-d8 (internal standard)	1.000
822	993553	hydroxy methyl furfural (HMF)	0.591
852	2948795	nonanoic acid	1.754
869	120809	benzeneacetaldehyde, alpha-ethylidene	0.072
878	277290	glyceryl monobutyrate	0.165
886	160361	delta-nonalactone	0.095
905	353542	glyceryl triacetate (Triacetin)	0.210
909	78219	2,4-decadienal	0.047
917	210011	1-butyl-2-pyrrolidinone	0.125
954	8223815	decanoic acid	4.891
1008	36450528	vanillin	21.679
1022	98587	undecanoic acid	0.059
1041	18188	vanillyl ethyl ether	0.011
1046	22831	ethyl vanillin	0.014
1057	54160	2-tridecanone	0.032
1066	78183	5-methyl-2-phenyl-2-hexenal	0.046
1077	634090	delta-decalactone	0.377
1109	2059600	lauric acid	1.225
1131	18753	ethyl laurate	0.011
1140	88386	mellein	0.053
1164	27742	delta-undecalactone	0.016
1173	31055	tridecanoic acid	0.018
1221	166680	gamma-dodecalactone	0.099
1248	472494	delta-dodecalactone	0.281
1264	212398	myristic acid	0.126
1290	22629	ethyl myristate	0.013
1392	525162	caffeine	0.312
1415	81331	methyl palmitate	0.048
1446	227475	delta-tetradecalactone	0.135
1487	82318	ethyl palmitate	0.049
1606	24559	methyl linoleate	0.015
1637	24358	methyl oleate	0.014
1668	43981	methyl stearate	0.026
1733	54946	ethyl linoelate	0.033
1740	56610	ethyl oleate	0.034
1777	21068	ethyl stearate	0.013
		Total (excluding internal standard)	**44.787**

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645	136338	heptanoic acid	0.081
655	271255	2-acetyl pyrrole	0.161
663	135720	ethyl dimethyl pyrazine isomer	0.081

85. The Product contains vanillin (MS Scan # 1008, 21.679 PPM), yet fails to detect *any* of the other marker compounds for vanilla – p-hydroxybenzaldehyde, p-hydroxybenzoic acid or vanillic acid.

86. The logical explanation for their absence in spite of the high level of vanillin is not because the Product lacks any vanilla, but that it contains a small amount such that these aromatic compounds are not detectable by advanced scientific means.

87. By using a drop of vanilla extract instead of not using any, defendant can credibly claim its Product has vanilla extract.

88. However, defendant cannot label the Product as "vanilla ice cream" because it fails to contain sufficient flavor from vanilla to characterize it.

89. The Product also contains maltol (MS Scan # 713, 0.752 PPM), an (artificial) synthetic flavor enhancer that is only present in real vanilla at levels close to 100 times lower than

identified here. *See* 21 C.F.R. § 172.515(b) ("Synthetic flavoring substances and adjuvants.").[36]

90. Maltol is well-known as a flavor enhancer which does not "contribute a flavor of its own," but increases sweetness and enhances the sensation of creaminess, attributes relevant to a vanilla ice cream product.[37]

91. The analysis also detected high levels of ethyl vanillin (MS Scan # 1046, 0.014 PPM), an artificial flavor with 3.5 times the strength of regular non-vanilla vanillin. *See* 21 C.F.R. § 182.60 ("Synthetic flavoring substances and adjuvants.").

92. Even at the small levels detected, ethyl vanillin contributes to the Product's vanilla taste, but it is sourced from petroleum byproducts instead of vanilla beans.

93. Since the coating contains artificial flavor which typically contains ethyl vanillin, the analysis excluded the coating and chocolate candies, to prevent dispersion or drift from the enrobing (application of chocolate coating) to the vanilla ice cream core.

94. One plausible explanation is that the chocolate coating contains a higher than usual amount of ethyl vanillin in order to "spike" the vanilla flavor, because defendant knows that ethyl vanillin is a permitted ingredient in chocolate coating but not in real vanilla ice cream.

95. Benzaldehyde (MS Scan # 542, 0.300 PPM), a compound not associated with real vanilla, but added to vanilla flavoring preparations to enhance vanilla was also detected.

VI. Non-Vanilla Flavor Components are Inconsistent with a Product Identified as "Vanilla Ice Cream"

96. Even if the non-vanilla vanillin, maltol and benzaldehyde are naturally derived and from natural sources, they are still "natural flavoring compounds that resemble, simulate and/or

[36] 21 C.F.R. § 172.515(b) ("Synthetic flavoring substances and adjuvants."); D. T. Le Blanch, "*Maltol and ethyl maltol from larch tree to successful food additives*," Food Technol. 26 (1989): 78-87.
[37] 21 C.F.R. § 172.515(b) ("Synthetic flavoring substances and adjuvants."); Maltol, UL Prospector, Bryan W. Nash & Sons Ltd.1.

enhance vanilla flavor but are not derived from vanilla bean," and thus "would not comply with the intent of the flavor provisions of Category I ice cream." *See* Exhibit "G," Letter from Taylor M. Quinn, Associate Director for Compliance, Bureau of Foods, to Glenn P. Witte, International Association of Ice Cream Manufacturers, May 31, 1979 ("Quinn Letter, May 31, 1979").

97. Vanillin, maltol and benzaldehyde are ingredients often used in a flavor identified as "Vanilla With Other Natural Flavors" or "Vanilla WONF."

98. These "Other Natural Flavors" enhance, simulate and extend vanilla, allowing the Product to use less real vanilla to achieve the same vanilla taste.

99. However, a "product identified as 'Vanilla Ice Cream' is subject to the category 1 ice cream requirements and, therefore, must contain only the characterizing flavor derived from vanilla beans" instead of a vanilla WONF ingredient because "the standard for ice cream does not provide for the label designation of 'With other [natural] flavors' (WONF)." Exhibit "A," Summers Letter, April 10, 1979.

100. "[N]atural flavors not derived from vanilla beans," like maltol and non-vanilla vanillin, "may be used in combination with the standardized items included under 21 CFR 169 (vanilla-vanillin extract or vanilla-vanillin flavoring) for category II vanilla flavored ice cream provided that the flavoring contributed by or derived from the vanilla beans predominates" and they are fully disclosed as same. Exhibit "H," Letter from Taylor M. Quinn to Kenneth Basa, National Food Ingredient Company, August 22, 1979 ("Quinn Letter, August 22, 1979") and Letter from Basa to Quinn, July 31, 1979 ("Basa Letter, July 31, 1979"); *See* 21 C.F.R. §135.110(f)(2)(ii) ("Category II").

101. The Product is a Category 3 if the "artificial flavor [from non-vanilla vanillin and maltol] predominates. 21 C.F.R. §135.110(f)(2)(iii) ("Category 3") .

102. Non-vanilla vanillin, ethyl vanillin, benzaldehyde and maltol are permitted in Category II or Category III vanilla ice cream products as opposed to Category 1, which is the way the Product is represented.

103. The Product is represented in a manner which is deceptive to consumers.

VII. Product Purports to be Vanilla Ice Cream Modified by Express Nutrient Content Claims[38]

A. Differences between "Vanilla Ice Cream" and "Vanilla Ice Cream" Modified by Express Nutrient Content Claims

104. Until the early 1990s, any product with "ice cream" (or a standardized food) in its name had to meet requirements set in its standards of identity which required a dairy product with "not less than 10 percent milkfat, nor less than 10 percent nonfat milk solids."[39]

105. Around this time, express nutrient content claims were introduced, which meant companies could make "direct statement[s] about the level (or range) of a nutrient in a food, e.g., 'low sodium' or 'contains 100 calories,'" milkfat or sugar.[40]

106. In all other respects, the product has to maintain conformity to the standard so consumers will not expect a product to taste and/or perform in a certain way when that product departs in significant and/or material ways from what they are accustomed to receiving.

107. For example, instead of requiring ice cream to have 10% milkfat, "lowfat ice cream" could contain a maximum of 3 grams of total fat per serving (½ cup) and "nonfat ice cream" could contain less than 0.5 grams of total fat per serving.[41]

108. A reduced fat ice cream is required to have 25% less fat than a reference product.[42]

109. Modified versions of standardized foods were permitted to deviate from the standard

[38] 21 CFR § 130.10 – Requirements for foods named by use of a nutrient content claim and a standardized term.
[39] 21 C.F.R. § 135.110(a)(2).
[40] 21 C.F.R. § 101.13(b)(1).
[41] 21 21 C.F.R. § 130.10(a).
[42] 21 C.F.R. § 101.62(b)(4)

with respect to performance characteristics like moisture content, food solids content requirements, or processing conditions.

110. In modified foods, the ingredients were required to be those permitted by the particular standard, subject to certain exceptions.[43]

111. If an ingredient or component was specifically required by the standard, it could not be replaced or exchanged with a similar ingredient from another source unless the standard allows it, i.e., vegetable oil shall not replace milkfat in light sour cream).[44]

112. If a standard prohibited an ingredient, that ingredient could not be added in a modified version of the food.[45]

113. All ingredients required by a standard have to still be present in a significant amount in a modified version of the food, *viz*, at least that amount that is required to achieve the technical effect of that ingredient in the food.[46]

B. The Product's Representation as a "Vanilla Reduced Fat Ice Cream" are Misleading

114. The Product is represented as a Modified Versions of Vanilla Ice Cream, which is misleading and fails to comply with the requirements for express nutrient content claims for standardized foods.

115. Vanilla ice cream modified by an express nutrient content claim still requires that the flavor is derived exclusively from the characterizing flavor, vanilla, because vanilla is a required ingredient for adherence to the standardized food.

116. The standard for vanilla ice cream does not permit the Products to replace or

[43] 21 C.F.R. § 130.10(d)(1).
[44] 21 C.F.R. § 130.10(d)(2).
[45] 21 C.F.R. § 130.10(d)(3).
[46] 21 C.F.R. § 130.10(d)(4).

substitute flavors obtained from a non-vanilla source for flavors obtained from the vanilla plant, i.e., vanilla flavoring or vanilla extract. *See* 21 C.F.R. § 130.10(d)(2).[47]

117. Vanilla ice cream modified by an express nutrient content claim does not permit non-vanilla bean derived flavors in a Category 1 vanilla ice cream. *See* 21 C.F.R. § 130.10(d)(3).[48]

118. The prohibited ingredient or ingredient component in the Reduced Fat Vanilla Ice Cream Product is the non-vanilla part of the "Natural Flavor."

119. Because non-vanilla flavor is not permitted by the standard in vanilla ice cream, it is by definition used in excess of levels provided for by the standard.

120. Even if non-vanilla flavors were permitted in a product labeled "vanilla ice cream," the Product's labels would still be misleading because the ingredient list does not identify the "Natural Flavors" with an asterisk, such as "*Ingredient(s) not in regular vanilla light ice cream" or "*Ingredient(s) in excess of amount permitted in regular vanilla light ice cream."[49]

C. Express Nutrient Content Claim Does Not Relate to Flavoring Used in Ice Creams

121. The only authorized deviations from the standard by express nutrient content claims are those that (1) are necessary to make the nutrient content claim, (2) ensure that the food meets the performance characteristics of the traditional standardized food and (3) ensure the food is not

[47] 21 C.F.R. § 130.10(d)(2) ("An ingredient or component of an ingredient that is specifically required by the standard (i.e., a mandatory ingredient) as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169 of this chapter, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream); 21 C.F.R. § 135.110(f)(2)(i)

[48] 21 C.F.R. § 130.10(d)(3) ("An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section."); 21 C.F.R. § 135.110(f)(2)(i)

[49] 21 C.F.R. § 130.10(f)(2) ("Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement "*Ingredient(s) not in regular ___" (fill in name of the traditional standardized food) or "*Ingredient(s) in excess of amount permitted in regular ___" (fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.); 21 C.F.R. § 135.110(f)(2)(i).

nutritionally inferior to the traditional standardized food.

122. The allowed modifications to standardized foods relate to direct statements about the level or range of a nutrient in the food such as fat, sugar and calories, as opposed to the amount and composition of the flavoring.

123. Modification of a food by an express nutrient content claim does not provide justification or authority for deviating from the vanilla flavor requirement of a Category 1 ice cream because:

- The nutrient content claims modify the term "ice cream" by adjusting the nutrient composition of the Products;
- Vanilla ingredients are not nutrients, but flavorings;
- Vanilla extract and vanilla flavorings are insignificant sources of calories, fat, sugar and other nutrients which are subject to express nutrient content claims;
- Should a company wish to use less vanilla in an ice cream, it can easily do so by designating that product with the term "vanilla flavored" or a similar variation
- The amount, type and/or percentage of vanilla is not permitted to be adjusted on the basis of making a nutrient content claim because the amount of vanilla has no functional or technical effect on those aspects of the food which are modified by the nutrient content claim.

VIII. Conclusion

124. Defendant's branding and packaging of the Product is designed to – and does – deceive, mislead, and defraud plaintiff and consumers.

125. Defendant sold more of the Product and at higher prices than it would have in the absence of this misconduct, resulting in additional profits at the expense of consumers like

plaintiffs.

126. The value of the Product that plaintiffs purchased and consumed was materially less than their value as represented by defendant.

127. Had plaintiffs and class members known the truth, they would not have bought the Product or would have paid less for them.

128. As a result of the false and misleading labeling, the Product is sold at a premium price, approximately no less than $5.99 for boxes containing 6 bars of 1.63 FL OZ, excluding tax, compared to other similar products represented in a non-misleading way.

Jurisdiction and Venue

129. Jurisdiction is proper pursuant to 28 U.S.C. § 1332(d)(2) (Class Action Fairness Act of 2005 or "CAFA").

130. Under CAFA, district courts have "original federal jurisdiction over class actions involving (1) an aggregate amount in controversy of at least $5,000,000; and (2) minimal diversity[.]" *Gold v. New York Life Ins. Co.*, 730 F.3d 137, 141 (2d Cir. 2013).

131. Plaintiff Sherise Richardson is a citizen of New York.

132. Defendant Mars Wrigley Confectionery US, LLC is a Delaware limited liability company with a principal place of business in Hackettstown, Warren County, New Jersey and upon information and belief, at least one of its members is not a citizen of New York.

133. Venue is proper because plaintiff Richardson resides in this District.

134. Venue is supported because many class members reside in this District.

135. This court has personal jurisdiction over defendant because it conducts and transacts business, contracts to supply and supplies goods within New York.

Parties

136. Plaintiff Sherise Richardson is a citizen of Middletown, Orange County, New York.

137. Plaintiff Dorianne Gatto is a citizen of Staten Island, Richmond County, New York.

138. Defendant Mars Wrigley Confectionery US, LLC is a Delaware limited liability company with a principal place of business in Hackettstown, New Jersey, Warren County.

139. During the relevant statutes of limitations, plaintiffs purchased the Product within their district and/or State for personal consumption and/or use in reliance on the representations the Product's flavor was exclusively from real vanilla and that it did not contain flavors designed to mimic and imitate vanilla.

140. Plaintiff Richardson purchased the Product at store(s) including Walmart and ShopRite in Middletown, New York, during the spring, summer and fall of 2019.

141. Plaintiff Gatto purchased the Product at store(s) including ShopRite on Hylan Boulevard on Staten Island, on multiple occasions during 2019 and 2020 and most recently in March 2020.

142. Plaintiffs bought the Product because they liked the product type for its intended use and expected its vanilla flavor to come from only real vanilla because if the flavor was provided by flavors which modified or enhanced the vanilla, they expected that to be indicated on the front label.

143. Plaintiffs would buy the Product again if assured its vanilla taste was provided solely from the vanilla plant and not from modifiers and enhancers which imitate vanilla.

Class Allegations

144. The class will consist of all purchasers of the Product who reside in New York during the applicable statutes of limitations.

145. Common questions of law or fact predominate and include whether defendant's representations were and are misleading and if plaintiffs and class members are entitled to damages.

146. Plaintiffs' claims and basis for relief are typical to other members because all were subjected to the same unfair and deceptive representations and actions.

147. Plaintiffs are adequate representatives because their interests do not conflict with other members.

148. No individual inquiry is necessary since the focus is only on defendant's practices and the class is definable and ascertainable.

149. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest relative to the scope of the harm.

150. Plaintiffs' counsel is competent and experienced in complex class action litigation and intends to adequately and fairly protect class members' interests.

151. Plaintiffs seek class-wide injunctive relief because the practices continue.

New York General Business Law ("GBL"), §§ 349 & 350
(Consumer Protection Statutes)

152. Plaintiffs incorporate by reference all preceding paragraphs.

153. Plaintiffs and class members desired to purchase and consume products which were as described and marketed by defendant and expected by reasonable consumers, given the product type.

154. Defendant's acts and omissions are not unique to the parties and have a broader

impact on the public.

155. Defendant misrepresented the substantive, quality, compositional, organoleptic and/or nutritional attributes of the Product.

156. The amount and proportion of the characterizing component, vanilla, has a material bearing on price or consumer acceptance of the Products because consumers expect the ice cream portion of the Product to contain only vanilla flavor from vanilla beans, and will pay more for such Products.

157. Reasonable consumers do not expect vanilla ice cream labeled only with "vanilla" to contain artificial vanilla, *viz*, vanillin – nor added enhancers like maltol.

158. Through omitting these other flavors from the front label, defendant deceived consumers as to the source of the Product's flavor and labeled the Product contrary to the requirements of New York and the FDA, deceiving consumers.

159. Plaintiffs relied on the statements, omissions and representations of defendant, and defendant knew or should have known the falsity of same.

160. Plaintiffs and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Negligent Misrepresentation

161. Plaintiffs incorporate by reference all preceding paragraphs.

162. Defendant misrepresented the substantive, quality, compositional, organoleptic and/or nutritional attributes of the Product.

163. The amount and proportion of the characterizing component, vanilla, has a material bearing on price or consumer acceptance of the Products because consumers expect the ice cream portion of the Product to contain only vanilla flavor from vanilla beans, and will pay more for such

Products.

164. Reasonable consumers do not expect vanilla ice cream labeled only with "vanilla" to contain artificial vanilla, *viz*, vanillin – nor added enhancers like maltol.

165. Through omitting these other flavors from the front label, defendant deceived consumers as to the source of the Product's flavor and labeled the Product contrary to the requirements of New York and the FDA, deceiving consumers.

166. Defendant had a duty to disclose and/or provide non-deceptive marketing of the Product and knew or should have known same were false or misleading.

167. This duty is based on defendant's position as an entity which has held itself out as having special knowledge and experience in the production, service and/or sale of the product type.

168. The representations took advantage of consumers' cognitive shortcuts made at the point-of-sale and their trust in defendant, a well-known and respected brand or entity in this sector.

169. Plaintiffs and class members reasonably and justifiably relied on these negligent misrepresentations and omissions, which served to induce and did induce, the purchase of the Product.

170. Plaintiffs and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Breaches of Express Warranty, Implied Warranty of Merchantability and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq*.

171. Plaintiffs incorporate by reference all preceding paragraphs.

172. The Product were manufactured, labeled and sold by defendant and warranted to plaintiffs and class members that they possessed substantive, functional, nutritional, qualitative, compositional, organoleptic, sensory, physical and other attributes which they did not.

173. The amount and proportion of the characterizing component, vanilla, has a material

bearing on price or consumer acceptance of the Products because consumers expect the ice cream portion of the Product to contain only vanilla flavor from vanilla beans, and will pay more for such Products.

174. Reasonable consumers do not expect vanilla ice cream labeled only with "vanilla" to contain artificial vanilla, *viz*, vanillin – nor added enhancers like maltol.

175. Through omitting these other flavors from the front label, defendant deceived consumers as to the source of the Product's flavor and labeled the Product contrary to the requirements of New York and the FDA, deceiving consumers.

176. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.

177. This duty is based, in part, on defendant's position as one of the most recognized companies in the nation in this sector.

178. Plaintiffs provided or will provide notice to defendant, its agents, representatives, retailers and their employees.

179. Defendant received notice and should have been aware of these misrepresentations due to numerous complaints by consumers to its main office over the past several years regarding the Product, of the type described here.

180. The Product did not conform to its affirmations of fact and promises due to defendant's actions and were not merchantable.

181. Plaintiffs and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Fraud

182. Plaintiffs incorporate by reference all preceding paragraphs.

183. The amount and proportion of the characterizing component, vanilla, has a material bearing on price or consumer acceptance of the Products because consumers expect the ice cream portion of the Product to contain only vanilla flavor from vanilla beans, and will pay more for such Products.

184. Reasonable consumers do not expect vanilla ice cream labeled only with "vanilla" to contain artificial vanilla, *viz*, vanillin – nor added enhancers like maltol.

185. Through omitting these other flavors from the front label, defendant deceived consumers as to the source of the Product's flavor and labeled the Product contrary to the requirements of New York and the FDA, deceiving consumers.

186. Defendant's fraudulent intent is evinced by its failure to accurately identify the Product on the front labels, when it knew its statements were neither true nor accurate and could mislead consumers.

187. Plaintiffs and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Unjust Enrichment

188. Plaintiffs incorporate by reference all preceding paragraphs.

189. Defendant obtained benefits and monies because the Product was not as represented and expected, to the detriment and impoverishment of plaintiffs and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiffs demand a jury trial on all issues.

WHEREFORE, Plaintiffs pray for judgment:

1. Declaring this a proper class action, certifying plaintiffs as representatives and the undersigned as counsel for the class;
2. Entering preliminary and permanent injunctive relief by directing defendant to correct the challenged practices to comply with the law;
3. Injunctive relief to remove, correct and/or refrain from the challenged practices and representations, and restitution and disgorgement for members of the class pursuant to the applicable laws;
4. Awarding monetary damages and interest pursuant to the common law and other statutory claims;
5. Awarding costs and expenses, including reasonable fees for plaintiffs' attorneys and experts; and
6. Other and further relief as the Court deems just and proper.

Dated: May 13, 2020

Respectfully submitted,

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7:19-cv-10860-KMK
United States District Court
Southern District of New York

Sherise Richardson, Dorianne Gatto, individually and on behalf of all others similarly situated,

Plaintiffs,

- against -

Mars Wrigley Confectionery US, LLC,

Defendant

First Amended Class Action Complaint

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Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information, and belief, formed after an inquiry reasonable under the circumstances, the contentions contained in the annexed documents are not frivolous.

Dated: May 13, 2020

/s/ Spencer Sheehan
Spencer Sheehan